UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., *Plaintiff*, v. BIONPHARMA INC., *Defendant*.	**Public Version** C.A. No. 21-1286-LPS [redacted] **JURY TRIAL DEMANDED**

DEFENDANT BIONPHARMA'S ANSWER, DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S FIRST AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

Defendant Bionpharma Inc. ("Defendant" or "Bionpharma"), by its undersigned counsel, for its Answer to the First Amended and Supplemental Complaint for Patent Infringement (D.I.[1] 89) ("First Amended Complaint") filed by Plaintiff Azurity Pharmaceuticals, Inc. ("Plaintiff" or "Azurity")), states as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Bionpharma denies all allegations in Plaintiff's First Amended and Supplemental Complaint except those specifically admitted below:

THE NATURE OF THE ACTION

1. Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that Plaintiff's First Amended and Supplemental Complaint for Patent Infringement purports to state an action for infringement of U.S. Patent Nos. 11,040,023 (the "'023 patent") under Title 35 of the United States Code based on Bionpharma filing of Abbreviated New Drug Application ("ANDA") No. 212408

[1] All "D.I." citations are to the docket in the instant action, 21-1286-LPS, unless otherwise specified.

("Bionpharma's ANDA") with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) *et seq.*, concerning a 1 mg/mL enalapril maleate oral solution ("Bionpharma's ANDA product"). Bionpharma denies all remaining allegations of paragraph 1.

THE PARTIES

2. Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 2, and on that basis denies these allegations.

3. Bionpharma admits that it is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 600 Alexander Rd., #2-4B, Princeton, NJ 08540. The remaining allegations of paragraph 3 contain legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

JURISDICTION AND VENUE

4. Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

5. Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

6. Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Bionpharma does not contest personal jurisdiction in this Judicial District for the limited purposes of this action only. Bionpharma denies all remaining allegations of paragraph 6.

7. Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma does not contest venue for the purposes of this action only. Bionpharma denies all remaining allegations of paragraph 7.

AZURITY'S EPANED® PRODUCT

8. Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 8, and on that basis denies these allegations.

9. Bionpharma admits that according to the electronic records of the FDA's publication entitled "*Approved Drug Products with Therapeutic Equivalence Evaluations*," commonly known as the "Orange Book," the FDA has approved Epaned® enalapril maleate oral solution, 1mg/mL. Bionpharma further admits that, according to the most recent version of the prescribing information for Epaned® available on FDA's website, it is approved for treatment of hypertension in adults and children older than one month, symptomatic heart failure, and asymptomatic left ventricular dysfunction. Bionpharma denies the remaining allegations of Paragraph 9.

PATENT-IN-SUIT

10. Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that what purports to be a copy of the '023 patent is attached to this First Amended and Supplemental Complaint as Exhibit A; that the '023 patent is entitled "Enalapril Formulations" and bears an issue date of June 22, 2021. Bionpharma denies any suggestion that the '023 patent is valid or enforceable. Bionpharma lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in paragraph 10, and on that basis denies these allegations.

11. Denied.

12. Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, admitted.

13. Denied.

14. Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, denied.

[ALLEGED] INFRINGEMENT BY BIONPHARMA

15. Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that it sent a letter dated July 6, 2021, which served as written notification pursuant to 21 U.S.C. § 355(j)(2)(B) of Bionpharma's ANDA and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '023 patent, and which satisfied all statutory, legal, and regulatory requirements. Bionpharma denies all remaining allegations of paragraph 15.

16. Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, admitted.

17. Paragraph 17 contains legal conclusions and allegations to which no answer is required, to the extent an answer is required, Bionpharma admits that it continues to market its ANDA product. Bionpharma denies all remaining allegations of Paragraph 17.

18. Denied.

19. Denied.

20. Denied.

CLAIMS FOR RELIEF

Count I—[Alleged] Infringement of the '023 Patent Under 35 U.S.C. § 271(e)(2)(A)

21. Bionpharma incorporates its answers to the preceding paragraphs as if fully set forth herein.

22. Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that it has filed with the FDA Bionpharma's ANDA seeking FDA approval of its ANDA product. Bionpharma denies all remaining allegations of paragraph 22.

23. Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

24. Denied.

25. Denied.

Count II—[Alleged] Infringement of the '023 Patent Under 35 U.S.C. § 271(a)-(c)

26. Bionpharma incorporates its answers to the preceding paragraphs as if fully set forth herein.

27. Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Bionpharma admits that FDA provided final approval of Bionpharma's ANDA. Bionpharma denies all remaining allegations of paragraph 27.

28. Denied.

29. Denied.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

PRAYER FOR RELIEF

Bionpharma denies Plaintiff is entitled to any of the relief requested in its Prayer for Relief or otherwise.

BIONPHARMA'S ADDITIONAL DEFENSES

Bionpharma asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the First Amended Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(INVALIDITY OF THE '023 PATENT)

The claims of the '023 patent are invalid and/or unenforceable under 35 U.S.C. § 101 *et seq*., including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(NO INFRINGEMENT OF THE '023 PATENT)

The filing of Bionpharma's ANDA, and the manufacture, use, offer for sale, sale, or importation of Bionpharma's ANDA product, do not and will not infringe, either literally or under the doctrine of equivalents, either directly or indirectly, any valid and enforceable claim of the '023 patent, including because Bionpharma has a license to the '023 patent, and including because Azurity has exhausted its patent rights (first sale doctrine).

THIRD AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Azurity's First Amended Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted, including because Azurity has no cause of action for alleged infringement under 35 U.S.C.§ 271(e), including because the instant action is precluded on *res judicata* grounds, and including because Azurity has no cause of action for infringement on patent exhaustion/first sale and licensing grounds.

FOURTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Azurity fails to state a proper claim for an exceptional case and/or willful infringement, including because Azurity has failed to plead proper pre-suit knowledge of the patent-in-suit on the part of Bionpharma.

FIFTH AFFIRMATIVE DEFENSE
(*RES JUDICATA*)

Azurity's First Amended Complaint is barred on *res judicat*a grounds, including on claim preclusion grounds as Azurity's First Amended Complaint asserts the same cause of action that was previously litigated and resolved in Bionpharma's favor in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), and including on collateral estoppel grounds.

SIXTH AFFIRMATIVE DEFENSE
(WAIVER-ESTOPPEL-UNCLEAN HANDS)

Azurity's claims for relief are barred by one or more of the equitable doctrine of waiver, estoppel, and/or unclean hands.

SEVENTH AFFIRMATIVE DEFENSE
(NO INJUNCTIVE RELIEF)

Azurity's claims for injunctive relief are barred because Azurity has brought this case in bad faith, has not been irreparably harmed, the balance of hardships is not in Azurity's favor, and the public interest is no served by granting injunctive relief.

EIGHTH AFFIRMATIVE DEFENSE
(NO DAMAGES)

Azurity's claims for damages are limited and/or barred under 35 U.S.C. §§ 286 and 287.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSES

Bionpharma reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendant Bionpharma Inc. ("Bionpharma"), by way of its attorneys, hereby states for its Counterclaims against Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity" or "Plaintiff"), the following:

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent No. 11,040,023 (the "'023 patent") (the "Patent-In-Suit"). Upon information and belief, a true and correct copy of the '023 patent is attached to the First Amended and Supplemental Complaint as Exhibit A.

2. These Counterclaims also seek injunctive relief, treble damages, and other relief under Federal antitrust laws to remedy plainly anticompetitive conduct by Azurity.

PARTIES

3. Bionpharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 600 Alexander Rd., #2-4B, Princeton, NJ 08540. Bionpharma is in the business of, among other things, selling pharmaceutical drug products.

4. Upon information and belief, Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801. Upon information and belief, Azurity is the successor-in-interest to Silvergate Pharmaceuticals, Inc.

JURISDICTION

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Sherman Antitrust Act, 15 U.S.C. §§ 2 and 26.

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1338(a), and 1367(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under 15 U.S.C. § 1 *et seq*.

7. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Bionpharma and Azurity arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and based on an actual controversy between Bionpharma and Azurity arising under the Federal antitrust laws, 15 U.S.C. § 1 *et seq*.

8. This Court has personal jurisdiction over Azurity based on, *inter alia*, the filing of this lawsuit in this jurisdiction.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), and 15 U.S.C. §§ 15 and 22.

FACTS COMMON TO ALL COUNTS

10. On or about June 22, 2021, the United States Patent and Trademark Office ("PTO") issued the '023 patent.

11. Upon information and belief, Azurity is the assignee of the '023 patent.

12. Azurity purports and claims to have the right to enforce the '023 patent.

13. In 2016, Bionpharma contracted with CoreRx, Inc. ("CoreRx"), a contract development and manufacturing organization, to, in collaboration with Bionpharma, develop a 1 mg/mL enalapril maleate oral solution as generic to Azurity's Epaned® (enalapril maleate) oral solution, 1 mg/mL, and to commercially manufacture that product for Bionpharma.

14. In 2018, Bionpharma prepared and filed with the U.S. Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 212408

("Bionpharma's ANDA"), which sought FDA approval for the 1 mg/mL enalapril oral solution product that Bionpharma developed in collaboration with CoreRx ("Bionpharma's ANDA product").

15. Pursuant to a Master Manufacturing Supply Agreement effective November 2020 ("MMSA"), CoreRx commercially manufactures and supplies Bionpharma's ANDA product. 21-1286 D.I. 105-1, Bionpharma's Extension Mot. Reply Ex. A.

16. On information and belief, on or about March 26, 2018, NovaQuest Capital Management ("NovaQuest") acquired a controlling interest in Azurity. 21-1286 D.I. 103-2, Bionpharma's Fla. Mot. to Intervene at Ex. B, M&A Deal Summary, NovaQuest Capital Management Acquires Azurity Pharmaceutical, MERGR.COM, https://mergr.com/novaquest-capital-management-acquires-azurity-pharmaceuticals (last visited Nov. 12, 2021).

17. On information and belief, on or about January 19, 2021, NovaQuest acquired a controlling interest in CoreRx. 21-1286 D.I. 103-2, Bionpharma's Fla. Mot. to Intervene at Ex. C, NovaQuest Private Equity Acquires CoreRx, Inc., BUSINESS WIRE (Jan. 19, 2021), https://www.businesswire.com/news/home/20210119005200/en/NovaQuest-Private-Equity-Acquires-CoreRx-Inc.

18. On information and belief, NovaQuest controls and/or dominates Azurity through an intermediate holding company, CutisPharma Intermediate Holdings Inc.

19. On information and belief, NovaQuest also controls and/or dominates CoreRx through the same intermediate holding company, CutisPharma Intermediate Holdings Inc.

20. According to Azurity's website (https://azurity.com/board-of-directors/) as of February 17, 2022, the members of Azurity's Board of Directors are: Nailesh Bhatt, Richard Blackburn, Vern Davenport, Jeff Edwards, Frank Leo, Amit Patel, and Dave Ritchie.

21. According to CoreRx's website (https://www.corerxpharma.com/about/board-of-directors/) as of February 17, 2022, the members of CoreRx's Board of Directors are: Nailesh Bhatt, Ajay Damani, Vern Davenport, Jeff Edwards, Frank Leo, Ashton Poole, and Nikhil Puri.

22. Four of seven members of Azurity's current board of directors— Messrs. Bhatt, Davenport, Edwards, and Leo—are also currently directors of CoreRx.

23. Between December 2021 and January 2022, five of seven members of Azurity's board of directors—Messrs. Bhatt, Davenport, Edwards, Leo, and Poole—were board members of CoreRx.

24. According to NovaQuest's website (https://www.novaquest.com/team/) as of February 17, 2022, Messrs. Davenport, Edwards and Poole are also Partners in NovaQuest.

25. Under the MMSA, Azurity is an affiliate of CoreRx because Azurity's ultimate parent (NovaQuest) is CoreRx's ultimate parent.

26. Azurity is a party to the MMSA because it is a commonly-owned affiliate of CoreRx.

27. On November 11, 2021, Azurity filed the First Amended and Supplemental Complaint for Patent Infringement in this action ("First Amended Complaint"), alleging that the filing of Bionpharma's ANDA and Bionpharma's subsequent commercial marketing of Bionpharma's ANDA product infringes the '023 patent.

FACTS RELATED TO COUNTS III-IV
(Monopolization and Attempted Monopolization Based on Sham Litigation)

I. REGULATORY BACKGROUND

28. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act of

2003, 21 U.S.C. §§ 335(b)(2) and 355(j), and 35 U.S.C. § 271(e), establish procedures designed to facilitate and speed competition in prescription drug markets from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

29. A company seeking to market a new pharmaceutical product in the United States must file a New Drug Application ("NDA") with the FDA demonstrating the safety and efficacy of the product. Products approved following submission of an NDA are referred to as "brand-name drugs" or "branded drugs."

30. To facilitate generic competition, the Hatch-Waxman Act provides that a company seeking to market a generic drug may file an ANDA with the FDA. The ANDA applicant is not required to conduct full clinical trials to demonstrate the safety and efficacy of the proposed generic drug. Instead, it may rely on the approved branded drug's profile for safety and efficacy.

31. The Hatch-Waxman Act also provides a framework for the holders of pharmaceutical patents to enforce their patents against generic competitors. When filing an ANDA, a generic manufacturer must certify whether its generic drug will infringe any patents listed in the FDA-published "Orange Book" as being associated with the branded drug. 21 U.S.C. § 355(j)(2)(A)(vii). For each listed patent, the ANDA applicant must make one of four possible certifications (respectively, the Paragraph I, II, III, and IV Certifications): (I) that no patent information on the branded drug has been submitted to the FDA; (II) that the patent has expired; (III) that the patent will expire on a stated date; or (IV) that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

32. Along with a Paragraph IV Certification, the applicant must provide notice to the patent holder of its invalidity or non-infringement position. 21 U.S.C. § 355(j)(2)(B)(i). The patent holder has forty-five days after receiving that notice to file a patent infringement suit. 21

U.S.C. § 355(j)(5)(B)(iii). Significantly, if an infringement suit is filed, FDA approval of the ANDA is stayed automatically until either thirty months have passed ("30-month stay") or a court rules that the patent is invalid or not infringed. *Id*.

33. Pharmacies often substitute for branded drugs, referred to as reference listed drugs ("RLDs"), with FDA-approved generic equivalents. Many states have "automatic substitution" laws that require pharmacists to substitute "AB-rated" generic versions for prescriptions written for the corresponding RLD unless the prescribing physician specifically requests otherwise. Conversely, generic drugs that are not AB-rated to the RLD cannot be automatically substituted for the RLD at the pharmacy level.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Epaned®

34. On September 20, 2016, the FDA approved Azurity's NDA No. 208686 for 1 mg/mL enalapril maleate oral solution, which Azurity sells under the trade name Epaned®. Enalapril maleate is an angiotensin-converting-enzyme ("ACE") inhibitor treatment originally approved by FDA in 1983 as a tablet formulation sold by Merck.

35. Epaned® is FDA approved to treat hypertension in children under six years of age, and is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction ("LVD").

36. Upon information and belief, the following categories of products may be used for the treatment of high blood pressure: (1) diuretics, (2) other angiotensin-converting enzyme (ACE) inhibitors (beyond enalapril); (3) angiotensin II receptor blockers (ARBs); (4) calcium channel blockers; (5) alpha blockers; (6) alpha-beta blockers; (7) beta blockers; (8) aldosterone antagonists; (9) renin inhibitors; (10) vasodilators; and (11) central-acting agents. However,

according to Azurity, none of these category of products, or the products that fall within these categories, is a viable competitive alternative to Epaned®.

37. Azurity presented evidence through its expert, Dr. Jeffrey Stec, that while diuretics are often the first medications used to treat high blood pressure, they are associated with increased urination, which could reduce potassium levels, which represents a disadvantage versus enalapril. 21-1286 D.I. 25-3, Decl. of Jeffrey A. Stec, Ph.D. ("8/19/21 Stec Decl.") ¶ 18.

38. Azurity presented evidence through its expert, Dr. Jeffrey Stec, that ACE inhibitors like enalapril help relax blood vessels by blocking the formation of a natural chemical that narrows blood vessels. *Id*. ¶ 19. However, according to Dr. Stec and Azurity, Epaned® is the only ready-to-use oral solution of enalapril, which caters to specific populations of patients that have trouble swallowing solid oral dosage forms.

39. Azurity presented evidence through its expert, Dr. Jeffrey Stec, that beta blockers are ordinarily prescribed with other blood pressure medications, *id*. ¶ 24, which is disadvantageous compared to agents like Epaned® which are usually not co-administered with other drugs.

40. Azurity presented evidence through its expert, Dr. Jeffrey Stec, that aldosterone antagonists are considered diuretics which can block a natural chemical that can contribute to high blood pressure. *Id*. ¶ 25.

41. Azurity presented evidence through its expert, Dr. Jeffrey Stec, that renin inhibitors should not be taken with ACE inhibitors due to a serious risk of complications. *Id*. ¶ 26.

42. Upon information and belief, enalapril maleate is currently available as a generic in tablet form sold by Sandoz Inc., Heritage Pharma, Wockhardt Ltd., and Taro Pharmaceuticals. According to Azurity and its irreparable harm expert, Epaned® has an advantage over these generic tablet formulations because Epaned®, as an oral solution, is more easily administrable to pediatric

and elderly patients. However, upon information and belief, Epaned® is priced much higher (on a per milligram bases of enalapril maleate API) than the generic enalapril maleate tablets that are available.

43. Enalapril maleate is also available as a tablet formulation sold under the trademark Vasotec®. According to Azurity and its irreparable harm expert, Epaned® has an advantage over Vasotec® because Epaned®, as an oral solution, is more easily administrable to pediatric and elderly patients. Moreover, upon information and belief, Epaned® is priced much higher than Vasotec®.

44. Azurity has contended that "there is ***no*** acceptable alternative to Epaned®." 21-1286 D.I. 52-6, Supplemental Decl. of Amit M. Patel ¶ 24 (emphasis in original). According to Azurity, other products are not reasonably interchangeable with Epaned® and therapeutically equivalent 1 mg/mL RTU enalapril maleate oral solution products, due to, among other factors, use, qualities, characteristics, and/or distinct customers or end uses (namely, children and elderly patients). According to Azurity, numerous other hypertension drugs are not available in oral solution form, and therefore cannot compete with Epaned®.

B. The First Wave Patents

45. In March of 2016, Azurity began filing patent applications directed to oral liquid formulations of enalapril, beginning with U.S. Patent Application No. 15/081,603 ("'603 application").

46. The '603 application was originally filed with 20 claims, three of which—claims 1, 12, and 20—were independent. All three independent claims required, in pertinent part, (i) about 1 mg/mL of enalapril; (ii) a buffer with specific concentrations of citric acid (1.82 mg/mL of citric acid for claim 1), or with 1.82 mg/mL of citric acid and 0.15 mg/mL of sodium citrate

dihydrate (claim 20) ("buffer limitation"); (iii) about 1 mg/mL of sodium benzoate as a preservative ("preservative limitation"); sucralose; water; and further required that the claimed liquids were stable under refrigerated conditions (5±3 °C) for at least 12 months.

47. On September 2, 2016, the PTO Examiner issued a first office action rejecting all 20 original claims of the '603 application as obvious over various prior art references. In the first office action, the Examiner suggested that Azurity "present[] evidence demonstrating criticality of the selection of the amounts and specific ingredients, such as evidence demonstrating that the prior art composition does not have the same long term stability as the instantly claimed composition."

48. On October 14, 2016, an interview with the Examiner took place where Azurity attempted to distinguish the pending '603 application claims from the prior art by comparing the components and concentrations of an example formulation (the E5 liquid in Example E in the specification of the '603 application) with the components and concentrations of the prior art formulations.

49. On January 17, 2017, the Examiner issued a second office action re-asserting essentially the same obviousness rejection, and additionally asserting an indefiniteness rejection because the claim term "stable" was undefined. With respect to obviousness, the Examiner rejected the comparison of the E5 formulation with the prior art, noting that the POSA would have removed any excipients from the prior art reconstituted formulations that were not needed for an oral liquid, and further that the E5 formulation was not representative of the broadest pending claims (claims 1 and 12) because those claims did not require sodium citrate dihydrate.

50. On February 3, 2017, Azurity filed an amendment ("the February 3, 2017 amendment") where it amended the pending claims and argued for patentability. With respect to the claim amendments, Azurity amended each of the three independent claims to define "stable,"

to address the Examiner's indefiniteness rejection. Azurity also narrowed the buffer limitation of the broader independent claims (claims 1 and 12) to require sodium citrate dihydrate at specific concentrations (0.15 mg/mL for claim 1), which was already required in the buffer limitation of narrower independent claim 20 (at 0.15 mg/mL).

51. In the Remarks section of the February 3, 2017 amendment, Azurity attempted to distinguish the amended claims from the prior art on two separate grounds. First, Azurity argued that the claimed stability was not obvious from the prior art formulations, and supported those arguments with a declaration from Dr. Gerold Mosher, one of the named inventors. Second, and independently, Azurity also distinguished the amended claims from the prior art based on the specific components and concentrations recited in the claims, going so far as to argue that "[i]n contrast [to the prior art formulations], the formulation of the present claims has only four ingredients along with enalapril and water." 18-1962 D.I. 257, Op. at 23 (quoting '603 Application Prosecution History ("'603 PH"), Feb. 3, 2017 Amendment at 17)).

52. Azurity also argued in connection with the February 3, 2017 Amendment that enalapril was inherently unstable in liquid formulations and that stability in the context of enalapril liquid formulations was unpredictable. Specifically, Azurity argued that "'the prior art does not provide any expectation that any particular combination would be successful for stable enalapril oral liquid formulations, much less any expectation that the combination of [sic] with enalapril, citric acid, sodium citrate, sodium benzoate, sucralose, and water at the recited concentrations and at a pH of less than about 3.5 would be successful in forming a stable enalapril liquid formulation.'" *Id*. at 23 (quoting '603 PH, Feb. 3, 2017 Amendment at 18). Azurity further argued that "[n]owhere does the prior art teach or suggest that a combination of enalapril, citric acid, sodium citrate, sodium benzoate, sucralose and water at the recited concentrations and at a pH of

less than about 3.5 at the claimed concentrations would have resulted in such a dramatic stabilization of enalapril." *Id*. at 26 (quoting '603 PH, Feb. 3, 2017 Amendment at 22).

53. Additionally, in the February 3, 2017 amendment, Azurity singled out the components and concentrations recited in the '603 application claims and emphasized their criticality to the claimed stability, and further argued that other components "are not needed or contemplated in the claimed enalapril liquid formulations as none of them are needed or necessary to produce an oral enalapril liquid formulation of the present claims that is stable." *Id*. at 61 (quoting '603 PH, Feb. 3, 20217 Amendment at 17).

54. Through its arguments made in connection with the February 3, 2017 amendment, Azurity disclaimed enalapril liquids that did not contain only the specific components recited in the '603 application claims.

55. From the arguments it made in connection with its February 3, 2017 amendment, Azurity knew or should have known that it had disclaimed enalapril liquids that did not contain only the specific components recited in the '603 application claims.

56. After Azurity amended claims 1 and 12 to remove sucralose at the Examiner's suggestion, the amended claims of the '603 application issued into U.S. Patent No. 9,669,008 B1 on June 6, 2017 ("'008 patent," 18-1962 D.I. 1-1, Compl. Ex. A). Thereafter, U.S. Patent Nos. 9,808,442 B2 ("'442 patent," 18-1962 D.I. 1-1, Compl. Ex. B), 10,039,745 B2 ("'745 patent," 18-1962 D.I. 1-1, Compl. Ex. C) and 10,154,987 B2 ("'987 patent," 19-1067 D.I. 1-1, Compl. Ex. A) (collectively, with the '008 patent, the "First Wave Patents") issued from continuation applications with very little substantive prosecution.

57. The '442 and '987 patents claim methods of treatment using the enalapril liquids claimed in the '008 and '745 patents, respectively. The claims of the '745 patent are essentially

the same as the claims of the '008 patent, except that the enalapril limitation and the concentration elements of the buffer and preservative limitations were slightly broadened in the '745 patent claims (from "about 1 mg/ml enalapril maleate" ('008 patent) to "about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof" ('745 patent); from "a buffer comprising about 1.82 mg/ml citric acid and about 0.15 mg/mL sodium citrate dihydrate" ('008 patent) to "a buffer comprising about 0.8 to about 3.5 mg/ml citric acid and about 0.1 to about 0.8 mg/ml sodium citrate" ('745 patent); and from "about 1 mg/ml of a preservative that is sodium benzoate" ('008 patent) to "about 0.7 to about 1.2 mg/ml sodium benzoate" ('745 patent)).

58. Claim 1 of the '008, which is representative of the '008 and '442 patent claims, recites as follows:

> Claim 1. A stable oral liquid formulation, comprising:
>
> (i) about 1 mg/ml enalapril maleate;
>
> (ii) a buffer comprising about 1.82 mg/ml citric acid and about 0.15 mg/mL sodium citrate dihydrate;
>
> (iii) about 1 mg/ml of a preservative that is sodium benzoate; and
>
> (iv) water;
>
> wherein the pH of the formulation is less than about 3.5; and
>
> wherein the formulation is stable at about 5±3° C. for at least 12 months; wherein the stable oral liquid formulation has about 95% or greater of the initial enalapril amount and about 5% w/w or less total impurities or related substances at the end of the given storage period.

59. Claim 1 of the '745 patent, which is representative of the '745 and '987 patent claims, recites as follows:

> Claim 1. A stable oral liquid formulation, comprising:
>
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;

(ii) a buffer comprising about 0.8 to about 3.5 mg/ml citric acid and about 0.1 to about 0.8 mg/ml sodium citrate;

(iii) about 0.7 to about 1.2 mg/ml sodium benzoate; and

(iv) water;

wherein the formulation is stable at about 5±3° C. for at least 12 months; and

wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

C. Bionpharma's ANDA and ANDA Product

1. Development

60. In 2016, Bionpharma contracted with CoreRx to, in collaboration with Bionpharma, develop Bionpharma's ANDA product.

61. In late 2016, Bionpharma worked with its outside litigation counsel and CoreRx to design its ANDA Product around Azurity's First Wave Patents by, *inter alia*, entirely eliminating a buffer from its ANDA product, and by using a preservative system (methylparaben-propylparaben) that was disclosed in the specification of the First Wave Patents, but not claimed, and was therefore dedicated to the public.

62. In designing its ANDA Product around Azurity's First Wave Patents, Bionpharma also expressly relied upon the claim amendments and disclaimers Azurity made during prosecution of the '603 application, described above, that estopped and barred Azurity as a matter of law from asserting that Bionpharma's design-around formulation could infringe the First Wave Patents.

2. Bionpharma's ANDA, Notice to Azurity, and Bionpharma's Offer of Confidential Access

63. Bionpharma thereafter filed its ANDA with the FDA on August 31, 2018. Bionpharma's ANDA was filed with Paragraph IV Certifications certifying that Bionpharma's ANDA and the product described therein would not infringe the '008, '442, and '745 patents, and

that those patents were invalid and/or unenforceable. Bionpharma's ANDA was later amended to include a Paragraph IV Certification for the '987 patent.

64. By letter dated October 30, 2018, Bionpharma sent Azurity written notification pursuant to 21 U.S.C. § 355(j)(2)(B) of Bionpharma's ANDA filing and Paragraph IV Certifications for the '008, '442, and '745 patents ("Bionpharma's Oct. 30, 2018 P-IV Notice Letter").

65. Bionpharma's October 30, 2018 P-IV Notice Letter included an offer of confidential access ("OCA") to Bionpharma's ANDA under the terms of the protective order agreed to by Bionpharma and Azurity that was entered in connection with prior litigation between the parties involving an ANDA Bionpharma had previously filed for a generic version of Azurity's predecessor product to Epaned®, the Epaned® Kit (*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, No. 16-cv-876-MSG (D. Del.) ("Prior Kit Litigation")). Azurity intentionally forwent the opportunity to obtain access to Bionpharma's ANDA because it would not agree to reasonable confidentiality restrictions on access to the ANDA.

66. In the Prior Kit Litigation, the same law firm—Wilson Sonsini Goodrich & Rosati ("Wilson Sonsini")—served as both Azurity's outside litigation counsel and Azurity's patent prosecution counsel. Consequently, the Stipulated Protective Order ("SPO") that the parties agreed to and that was entered in the Prior Kit Litigation included a ban on in-house access at Azurity to Bionpharma's ANDA, and a prosecution bar for those attorneys at Wilson Sonsini who would have access to Bionpharma's ANDA.

67. Moreover, after Azurity sued Bionpharma for alleged infringement of the First Wave Patents—*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS, 19-1067-LPS (D. Del.) ("First Wave Suits")—Azurity essentially agreed to the same confidentiality

terms, including a patent prosecution bar, in connection with the SPO entered in the First Wave Suits.

68. The confidentiality concerns that the SPOs in the Prior Kit Litigation and the First Wave Suits addressed were still relevant when Bionpharma sent Azurity its October 30, 2018 P-IV Notice Letter. Azurity still had prosecution of its Orange Book patents for Epaned® open, meaning that Azurity was still prosecuting patent applications directed to enalapril liquid formulations. As such, Bionpharma was justifiably concerned that allowing Azurity's in-house lawyers, and outside counsel who were involved in patent prosecution, access to Bionpharma's ANDA could lead to additional patent applications from Azurity attempting to cover Bionpharma's design-around formulation.

69. In light of the foregoing concerns, Bionpharma's OCA included the same ban on in-house access at Azurity to Bionpharma's ANDA, and the same prosecution bar for those attorneys at Wilson Sonsini who would have access to Bionpharma's ANDA that Azurity and its counsel had agreed to in the Prior Kit Litigation SPO.

70. On November 15, 2018, following the service of Bionpharma's October 30, 2018 P-IV Notice Letter, Azurity, through its counsel (Wilson Sonsini), contacted counsel for Bionpharma regarding Bionpharma's OCA. Azurity refused to accept Bionpharma's OCA, and struck key provisions such as the patent prosecution bar that Bionpharma had included to guard against disclosure of Bionpharma's confidential information to Wilson Sonsini attorneys who were prosecuting Azurity's Epaned® patents. Azurity's counsel said only that "we do not agree that the protective order that was entered in a prior case for a different ANDA, different patents, and a different product is relevant to the situation here."

71. Upon information and belief, Azurity and its litigation counsel (Wilson Sonsini) intentionally neglected their duty to carry out a reasonable pre-suit investigation into Azurity's infringement claims, because Azurity always intended to file suit against Bionpharma and obtain the benefit of the 30-month stay on FDA approval of Bionpharma's ANDA product, regardless of how completely Bionpharma had designed around Azurity's Firsts Wave Patents. In short, Azurity had no interest in whether Bionpharma's ANDA product actually infringed the First Wave Patents.

D. The First Wave Suits

1. The Suits, Discovery, and Azurity's Ever-Changing Infringement Theories

72. Despite Bionpharma's extensive design around, on December 12, 2018, Azurity began filing the First Wave Suits in this Court, without even reviewing Bionpharma's ANDA, asserting that Bionpharma's ANDA infringed the First Wave Patents.

73. The filing of the First Wave Suits triggered a 30-month stay of FDA approval of Bionpharma's ANDA, such that FDA could not approve Bionpharma's ANDA until the earlier of April 30, 2021 (30 months from the filing October 30, 2018 filing date of the 18-1962-LPS suit), or resolution of the first of the First Wave Suits, the 18-1962-LPS action, in Bionpharma's favor.

74. Following a Rule 16 scheduling conference held on December 3, 2019, pursuant to an interim agreement between Azurity and Bionpharma, Azurity agreed to accept production of Bionpharma's ANDA on an outside counsel eyes only basis with no access by Wilson Sonsini attorneys who were prosecuting Azurity's Epaned® patents, pending entry of a protective order in the First Wave Suits. Bionpharma produced its ANDA to Azurity on or about December 10, 2019.

75. Upon receiving Bionpharma's ANDA, Azurity, through its outside counsel, had documentary proof of the information that it had sought to avoid: that Bionpharma had designed around the First Wave Patents, including by entirely eliminating a buffer from its ANDA product,

and by using a preservative system (methylparaben-propylparaben) that was disclosed in the specification of the First Wave Patents, but not claimed, and was therefore dedicated to the public.

76. Consequently, upon receiving Bionpharma's ANDA, Azurity knew or should have known, through its outside counsel, that the First Wave Suits were objectively baseless.

77. Shortly after the close of pleadings, Azurity conceded that it could not prove literal infringement, and eventually entered into a stipulation that Bionpharma's ANDA product did not literally infringe the First Wave Patents.

78. However, over the course of the next two and a half years, Azurity continued to press an objectively baseless case against Bionpharma, alleging that Bionpharma's ANDA and ANDA product infringed the First Wave Patents under the doctrine of equivalents ("DOE").

79. With respect to the preservative limitation of the claims of the First Wave Patents, Azurity asserted that the methylparaben and propylparaben used in Bionpharma's ANDA product were equivalent to that limitation. This assertion was objectively baseless because Azurity had disclosed in the common specification enalapril liquids preserved with methylparaben-propylparaben, but never claimed such liquids; as a result, Azurity was foreclosed from asserting that such liquids were equivalent to the claimed liquids preserved with sodium benzoate under the disclosure-dedication doctrine.

80. With respect to the buffer limitation, Azurity repeatedly changed its infringement theory throughout fact discovery, first contending that hydrochloric acid (a strong acid) and sodium hydroxide (a strong base) used to adjust the pH of Bionpharma's ANDA product during the manufacturing process were equivalent to the buffer limitation. Azurity then contended that enalapril maleate itself in Bionpharma's ANDA product could satisfy the buffer limitation under the DOE. At one point, Azurity even contended that the methylparaben-propylparaben

preservatives used in Bionpharma's ANDA product, which Azurity had already contended were equivalent to the preservative limitation, also served as equivalent buffers. Azurity's ever-changing infringement theories for the buffer limitation expose that its infringement claims were objectively baseless; in fact, they reflect a futile search *for* an objective basis for its claims.

81. It was not until a week before service of opening expert reports that Azurity disclosed and centered on the infringement theory it took to trial for the buffer limitation: that maleic acid disassociated from enalapril maleate in Bionpharma's ANDA product would react with sodium hydroxide added to adjust the pH during the manufacturing process to form a maleic acid/sodium maleate buffer *in situ*. But as the trial showed, this theory proved equally baseless.

2. Trial

82. Prior to trial, Azurity dropped its assertion of the '008 and '442 patents, and only continued to assert infringement of certain claims of the '745 and '987 patents ("Asserted First Wave Patents").

83. During and after trial in connection with post-trial briefing, Azurity pressed its objectively baseless DOE infringement case.

84. In an attempt to avoid Bionpharma's legal defenses based on amendment-based estoppel, argument-based estoppel, and disclosure-dedication, Azurity raised only frivolous arguments.

85. With respect to amendment-based estoppel, Azurity argued that adding sodium citrate to the buffer limitation of the broader independent claims during prosecution of the '603 application was not a narrowing amendment. As Bionpharma pointed out in response, this argument was objectively baseless in light of Federal Circuit cases such as *Honeywell International Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1141 (Fed. Cir. 2004) ("[T]he

addition of a new claim limitation can give rise to a presumption of prosecution history estoppel, just like an amendment that narrows a preexisting claim limitation."). Indeed, prior to trial, Bionpharma notified Azurity and this Court that Azurity's position on this issue was "specious [and] frivolous," and supported an eventual exceptional case finding and attorney fees award against Azurity. 18-1962 D.I. 135, May 5, 2020 Hr'g Tr. 63:12-64:18.

86. Azurity knew or should have known, prior to trial and after trial, that its position that adding sodium citrate to the buffer limitation of the broader independent claims during prosecution of the '603 application was not a narrowing amendment, in an attempt to avoid amendment-based estoppel, was frivolous and objectively baseless.

87. With respect to Bionpharma's argument-based estoppel legal defense, Azurity argued at trial and afterward that the arguments it made during prosecution of the '603 application did not amount to a disclaimer because Azurity was allegedly simply distinguishing its claims from the prior art, and explaining why the prior art did not provide a reasonable expectation of success to achieving a stable enalapril oral liquid.

88. Azurity knew or should have known that its arguments against argument-based estoppel were frivolous and objectively baseless, as any reasonable competitor would have viewed its arguments during prosecution as a disclaimer of enalapril liquids that did not contain only the specific ingredients recited in the claims of the First Wave Patents.

89. With respect to Bionpharma's factual defense to infringement based on the buffer limitation—that Bionpharma's ANDA product did not contain a buffer, let alone one equivalent to the buffer limitation—Azurity continued to press forward with its contention that maleic acid would dissociate completely from enalapril maleate in Bionpharma's ANDA product and react with sodium hydroxide added in the penultimate step of Bionpharma's formulation process to form

a maleic acid/sodium maleate buffer, and that that alleged maleic acid/sodium maleate buffer would be equivalent to the buffer limitation ("Azurity's buffer limitation contention").

90. Azurity knew or should have known that its buffer limitation contention was objectively baseless, including because the contention would vitiate the buffer limitation. Specifically, there is no written description in the specification of the First Wave Patents of any enalapril liquid without a separate, independent buffer component. All of the enalapril liquids described in the specification use enalapril maleate and contain a separate independent buffer component, which is almost always citric acid and sodium citrate. Moreover, the only enalapril liquids described in the specification of the First Wave Patents as being stable for a least 12 months under refrigerated conditions, thus meeting the stability requirements of the claims, are the Example E liquids, which all contain a citric acid/sodium citrate buffer at specific concentrations, and sodium benzoate at about 1 mg/mL.

91. Azurity was intentionally trying to claim what Azurity did not invent, and what Bionpharma did invent: an enalapril liquid that is stable for at least 12 months under refrigerated conditions and that, unlike Azurity's claimed invention, does not contain a buffer.

92. No reasonable litigant could have realistically expected success on the merits of Azurity's infringement claims in the First Wave Suits.

3. The Court's Opinion and Final Judgment

93. This Court held a five day bench trial on February 1-5, 2021, and, on April 27, 2021, issued its Opinion finding the Asserted Claims not infringed by Bionpharma's ANDA product. 18-1962 D.I. 257, Op. at 1.

94. First, the Court found that Azurity was estopped from asserting DOE infringement, because (1) Azurity narrowed the scope of the buffer limitation of the '603 application claims

during prosecution to require sodium citrate, thereby relinquishing enalapril liquids that did not contain sodium citrate; and (2) because Azurity disclaimed enalapril liquids that did not contain only enalapril, water, and the precise excipients recited in the claims of the Asserted First Wave Patents. *Id*. at 54-66.

95. This Court specifically and expressly found that Azurity's argument that adding sodium citrate to the buffer limitation during prosecution of the '603 application was not a narrowing amendment lacked credibility. *Id*. at 66 n.12.

96. Second, the Court found that Azurity was further barred from pursuing DOE infringement because the methylparaben-propylparaben that Bionpharma's ANDA product used as an alternative to the claimed sodium benzoate was disclosed in the common specification, but not claimed, and was therefore dedicated to the public. *Id*. at 68-71.

97. This Court also went on to analyze DOE infringement in the event that Azurity is not estopped and barred and found that Azurity failed to prove DOE infringement of the buffer limitation. *Id*. at 64-68. First, the Court found that Azurity failed to carry its burden of proving the presence of a buffer in Bionpharma's ANDA product; alternatively, the Court found that, even if Azurity had proven the existence of a buffer in Bionpharma's ANDA product, the accused equivalent was substantially different from the buffer limitation (under both the function-way-result ("FWR") and insubstantial differences tests). *Id*. at 66-68.

98. On April 29, 2021, this Court entered final judgement in Bionpharma's favor. 18-1962 D.I. 270.

E. The Second Wave Patents and the Second Wave Suit

99. Shortly after Bionpharma filed its ANDA, Azurity began filing continuation patent applications that claimed priority to the First Wave Patents and that sought considerably broader

and different claim coverage, and eventually secured issuance of U.S. Patent Nos. 10,772,868 B2 ("'868 patent," 20-1256 D.I. 49-1, Second Am. Compl. Ex. A), 10,786,482 B2 ("'482 patent," 20-1256 D.I. 49-1, Second Am. Compl. Ex. B), and 10,918,621 B2 ("'621 patent," 20-1256 D.I. 49-1, Second Am. Compl. Ex. C) (collectively, "Second Wave Patents") in late 2020 and early 2021.

100. The First and Second Wave Patents share the same specification.

101. During prosecution of the U.S. Patent Application No. 16/177,159 ("'159 application"), which issued into the '482 patent, Azurity sought to claim enalapril liquids with *any* amount of citric acid/sodium citrate buffer, and with *any* preservative at *any* concentration. The PTO Examiner, however, recognized that Azurity was attempting to claim enalapril liquids that were nowhere described in the specification, and issued no less than three separate written description rejections, which required Azurity to narrow its '159 application claims to cover enalapril liquids with a specific range of concentrations of citric acid/sodium citrate buffer, and a specific preservative (either sodium benzoate or a paraben) at a specific concentration (about 1 mg/mL).

102. However, the Examiner also allowed Azurity to claim enalapril liquids with pHs and concentrations of citric acid/sodium citrate buffer beyond those of the Example E liquids—which are the only liquids described in the specification of the '159 application as being stable for at least 12 months under refrigerated conditions, and are thus the only liquids described in the specification that would meet the stability limitations of the claims of the '159 application—under the mistaken belief that Azurity could supplement its deficient specification with inventor declarations submitted after the '159 application was filed that described additional enalapril liquids as being stable, in violation of fundamental patent law. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) ("[A]n affidavit or declaration [submitted] during

prosecution . . . does not cure [a] lack of written description in the specification, [which is] required by statute.").

103. Azurity knew or should have known that it could not supplement its deficient specification with inventor declarations filed after Azurity filed the '159 application.

104. Azurity intentionally took advantage of the Examiner's misunderstanding. During prosecution of U.S. Patent Application Nos. 16/242,898 ("'898 application") and 16/991,575 ("'575 application"), which issued as the '868 and '621 patents, respectively, Azurity submitted an additional declaration from Dr. Mosher describing enalapril liquids stable at 12 months that use buffers beyond citric acid and sodium citrate. Azurity used the declaration to convince the Examiner to allow claims that do not require any particular kind of buffer, despite the fact that the only enalapril liquids described in the specification as being stable for at least 12 months under refrigerated conditions, the Example E liquids, each contain a citric acid/sodium citrate buffer.

105. Partly because Azurity was able to take advantage of the Examiner's failure to understand that a deficient specification cannot be cured by post-application filing declarations, and partly because the Examiner simply failed to appreciate the enormous breadth of the claims that Azurity filed in connection with the '159, '898, and '575 applications, Azurity was able to secure excessively broad claims in connection with its Second Wave Patents that go well beyond what is described and enabled in the specification.

106. Nevertheless, all of the issued claims of the Second Wave Patents require a buffer, which Bionpharma's ANDA product does not have.

107. Azurity instituted *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, 20-1256-LPS (D. Del.) ("Second Wave Suit") against Bionpharma on September 18, 2020, while the First

Wave Suits were pending, originally asserting infringement of only the '868 patent. Through two amended complaints, the '482 and '621 patents were added to the suit.

108. Fearing that the Court would not render a decision favorable for Azurity in the First Wave Suits by the April 30, 2021 expiration of the 30-month stay of FDA approval of Bionpharma's ANDA, Azurity moved for a preliminary injunction in connection with the Second Wave Patents on March 31, 2021, which the parties fully briefed. 18-1962 D.I. 231, 232, 245, 253.

109. Azurity sought to use the Second Wave Patents to block Bionpharma from launching its ANDA product upon expiration of the 30-month stay or a favorable decision from this Court in the First Wave Suits, whichever occurred earlier, despite the fact that the Second Wave Patents claimed liquids that were nowhere described in the specification of those patents, and were therefore invalid; consequently, any infringement suit against Bionpharma's ANDA based on the Second Wave Patent claims would have been objectively baseless.

110. Azurity knew or should have known that no reasonable litigant could have realistically expected success on the merits of Azurity's preliminary injunction motion and the Second Wave Suits.

111. On April 27, 2021, prior to expiration of the 30-month stay, this Court issued its Opinion after trial in the First Wave Suits (18-1962 D.I. 257), specifically finding that Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product. This finding collaterally estopped Azurity from pursuing infringement of the Second Wave Patents, and, on May 21, 2021, the Second Wave Suit was dismissed by stipulation.

F. Azurity's Continued Misuse of the PTO to Mire Bionpharma in Litigation

112. Upon information and belief, as part of a deliberate strategy to stifle generic competition, Azurity has kept patent prosecution of its Orange Book patents for Epaned® open with the goal of serially filing patent applications claiming essentially the same subject matter, and securing patents with patentably indistinct claims at different times, in order to sue generic competitors like Bionpharma continually and at different times, in a concerted and deliberate effort to drive up litigation costs for competitors like Bionpharma, and to mire Bionpharma in litigation for years.

113. For example, on March 25, 2016, Azurity filed the '603 application, that issued into the '008 patent on June 6, 2017.

114. On June 5, 2017, Azurity filed U.S. Patent Application No. 15/613,622, which issued as the '442 patent on November 7, 2017.

115. On November 2, 2017, Azurity filed U.S. Patent Application No. 15/802,341, which issued as the '745 patent on August 7, 2018.

116. On June 8, 2018, Azurity filed U.S. Patent Application No. 16/003,994, which issued as the '987 patent on December 18, 2018.

117. On October 31, 2018, Azurity filed the '159 application, which issued as the '482 patent on September 29, 2020.

118. On January 8, 2019, Azurity filed the '898 application, which issued as the '868 patent on September 15, 2020.

119. On August 12, 2020, Azurity filed the '575 application, which issued as the '621 patent on February 16, 2021.

120. On January 15, 2021, Azurity filed U.S. Patent Application No. 17/150,587 ("'587 application"), which issued as the '023 patent on June 22, 2021.

121. On April 12, 2021, Azurity filed U.S. Patent Application No. 17,228,024, which issued as U.S. Patent No. 11,141,405 ("'405 patent") on October 12, 2021.

122. The claims of the '442, '745, and '987 patents are patentably indistinct from, and cover essentially the same patentable subject matter as, the '008 patent.

123. The claims of the Second Wave Patents are patentably indistinct from, and cover essentially the same patentable subject matter as, the claims of the First Wave Patents. However, the claims of the Second Wave Patents are considerably broader than the claims of the First Wave Patents, and have no written description or enablement support in the common specification.

124. The claims of the '023 and '405 patents ("Third Wave Patents") are patentably indistinct from, and cover essentially the same patentable subject matter as, the claims of the First and Second Wave Patents. However, the claims of the Third Wave Patents are considerably broader than the claims of the First Wave Patents, and have no written description or enablement support in the common specification.

125. The Second and Third Wave Patent are all subject to terminal disclaimers Azurity filed during prosecution to overcome obviousness-type double patenting rejections that the PTO issued.

126. The Third Wave Patents share the same specification as the First and Second Wave Patents.

127. Upon information and belief, Azurity still has prosecution open for its Epaned® Orange Book patents.

128. The intent behind the patent certification process and notice letter process outlined in the Hatch-Waxman Act is to ensure that patent litigation involving an ANDA occurs and is resolved during the regulatory review process for the ANDA, such that, upon conclusion of that review process, if the ANDA-filer has prevailed in litigation, the ANDA-filer can launch its ANDA product with certainty that its ANDA product does not infringe the brand drug company's Orange Book patents.

129. In a deliberate attempt to undermine the intent behind the patent certification and notice letter process outlined in the Hatch-Waxman Act, Azurity has implemented a patent thicket strategy in order to keep Bionpharma mired in litigation involving patents that claim essentially the same subject matter, well past the approval of Bionpharma's ANDA, raising the risks and costs of launching Bionpharma's ANDA product.

130. Azurity's anticompetitive strategy of securing numerous continuation patents covering essentially the same invention and serially filing lawsuits against a generic competitor asserting essentially the same cause of action has been recently criticized by the FDA in a letter to the PTO as stifling generic competition and warranting further scrutiny and action by the PTO. D.I. 77-1, Bionpharma's Opp'n to Azurity's Mot. for Leave to File Am. Compl. Ex. A, Sept. 10, 2021 Ltr. from J. Woodcock, M.D., Acting FDA Comm'r, to A. Hirshfeld, performing the functions and duties of PTO Director, at 3; *id*. at 4-5 (Possible Misuse of the Patent System).

G. The Third Wave Patents and Suits, and Launch of Bionpharma's ANDA Product

131. Realizing not only that Bionpharma's design-around formulation did not infringe the First and Second Wave Patents, but that its effort to coerce Bionpharma through litigation and regulatory delay into abandoning its ANDA product was failing, on January 15, 2021—over two years after Bionpharma filed its ANDA with the FDA and the institution of the First Wave Suits—

Azurity filed with the PTO the '587 application and for the first time sought claims directed to enalapril liquids that did not require a buffer, in a blatant attempt at covering Bionpharma's ANDA product.

132. As with the enalapril liquids covered by the claims of the Second Wave Patents, the enalapril liquids covered by the claims of the '587 application find no written description or enablement support in the specification, and Azurity knew or should have known this.

133. Nevertheless, Azurity submitted during prosecution of the '587 application another declaration from Dr. Mosher, which, for the first time, described enalapril liquids without buffers, and included 12-week stability data for such liquids. Because of that declaration, and because of the Examiner's mistaken belief that Azurity could supplement its deficient specification with inventor declarations filed after the '587 application was filed, the Examiner allowed the claims of the '587 application, and the '023 patent issued on June 22, 2021.

134. On the date the '023 patent issued, Azurity filed the instant suit in the District of New Jersey, alleging that Bionpharma's ANDA infringed, and that Bionpharma's ANDA would infringe if commercially marketed, the '023 patent. D.I. 1.

135. Azurity knew or should have known, as of the filing date of the instant suit, that its infringement claims were objectively baseless, including because it knew or should have known that at least the enalapril liquids without buffers covered by the '023 patent claims have no written description support in the specification of the '023 patent.

136. Azurity knew or should have known that by virtue of NovaQuest's acquisition of CoreRx, Bionpharma has a license to the '023 patent, and thus Azurity knows or should know that its infringement claims in the instant suit are objectively baseless.

137. Azurity knew or should have known that by virtue of NovaQuest's acquisition of CoreRx, any patent rights Azurity has in Bionpharma's ANDA product have been exhausted by CoreRx's sale of Bionpharma's ANDA product to Bionpharma, and thus Azurity knows or should know that its infringement claims in the instant suit are objectively baseless.

138. No reasonable litigant could realistically expect success on the merits of Azurity's '023 patent claims.

139. On August 10, 2021, the FDA approved Bionpharma's ANDA product as an "AB-rated" generic alternative to Epaned®, and Bionpharma launched its ANDA product on or about August 17, 2021.

140. On August 19, 2021, two days after Bionpharma launched its ANDA product, Azurity filed a motion seeking a temporary restraining order, preliminary injunction, and other emergent relief (D.I. 24, "Azurity's Motion for Emergency Relief").

141. On September 10, 2021, the New Jersey court granted Bionpharma's § 1404(a) motion and transferred the instant action to this Court.

142. On October 12, 2021, Azurity secured issuance of the '405 patent from the PTO. The claims of the '405 patent are essentially duplicative over the claims of the '023 patent, and cover enalapril liquids that do not include a buffer.

143. On October 15, 2021, Azurity instituted *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1455-LPS (D. Del.), asserting that Bionpharma's ANDA and ANDA product infringe the '405 patent.

144. For the same reasons expressed above with respect to the '023 patent, Azurity knows or should know that its '405 patent infringement claims in the 21-1455 suite are objectively baseless.

145. On November 10, 2021, this Court denied Azurity's Motion for Emergency Relief (D.I. 24), finding that Bionpharma had come forward with persuasive evidence that the claims of the '023 patent lacked written description support in the specification and were not enabled, raising "substantial questions" regarding the validity of the '023 patent.

H. Azurity's Sham Suits Against CoreRx

146. On October 26, 2021, Azurity sued CoreRx—Azurity's commonly owned affiliate—for alleged infringement of the Third Wave Patents, in the Middle District of Florida, Tampa Division. *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 8:21-2515 (M.D. Fla.) ("Florida CoreRx suit").

147. The next day, on October 27, 2021, Azurity sued CoreRx in this Court for alleged infringement of the Third Wave Patents. *Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-lps (D. Del.) ("Delaware CoreRx suit").

148. In addition to the reasons discussed above with respect to its suits against Bionpharma, Azurity's suits against CoreRx were objectively baseless because Azurity and CoreRx are owned and controlled by the same private equity firm—NovaQuest.

149. The suits are objectively baseless for the simple reason that, by virtue of NovaQuest's ownership of and control over both Azurity and CoreRx, there can be no case or controversy between those two affiliates with respect to the alleged infringement of the Third Wave Patents.

150. Azurity and CoreRx are not parties having adverse legal interests by virtue of the fact that they are owned and controlled by the same entity—NovaQuest. Moreover, as the firms' common parent, NovaQuest has the power to control them, and thus to direct CoreRx to cease manufacturing for Bionpharma without involving the courts.

151. That Azurity and CoreRx are not parties having adverse legal interests is shown further by the fact that five out of the seven board members of Azurity's board of directors – including three NovaQuest Partners – sit on the seven-member board of CoreRx. Thus, Azurity and CoreRx are essentially part of the same company.

152. Shortly after Azurity filed the Florida and Delaware CoreRx suits, CoreRx—at, upon information and belief, Azurity's and/or NovaQuest's direction—contacted Bionpharma and demanded a renegotiation of the MMSA to, *inter alia*, modify the MMSA to falsely remove Azurity as an affiliate of CoreRx.

153. Upon information and belief, Azurity and/or NovaQuest, through CoreRx, sought renegotiation of the MMSA to falsely remove Azurity as an affiliate of CoreRx under the MMSA for the purpose of eliminating Bionpharma's non-infringement defense based on licensing.

154. Upon information and belief, Azurity has no intention of securing a damages award against CoreRx, Azurity's commonly-owned affiliate. Moreover, upon information and belief, with five of its directors also occupying five of CoreRx's seven board seats, Azurity had no need to seek an injunction to stop CoreRx from carrying out its contractual supply commitments to Bionpharma.

155. Upon information and belief, Azurity, at the direction of NovaQuest, sued CoreRx in an attempt to force Bionpharma into additional costly and distracting litigation – whether on behalf of CoreRx pursuant to the MMSA or as an intervenor – in order to protect itself against the feigned threat of an injunction against CoreRx's performance of its contractual obligation to supply Bionpharma with Bionpharma's ANDA product pursuant to the MMSA.

156. On November 26, 2021, Azurity filed notices of voluntary dismissal in the Florida and Delaware CoreRx suits.

157. Shortly before Azurity dismissed the Florida and Delaware CoreRx suits, Azurity entered into a settlement agreement with CoreRx whereby CoreRx agreed to stop supplying Bionpharma with Bionpharma's ANDA product. 21-1286 D.I. 128, Feb. 2, 2022 Azurity Ltr. Ex. B, *Bionpharma Inc. v. CoreRx, Inc.*, C.A. No. 21-10656 (JGK) (S.D.N.Y.), D.I. 56, Jan. 25, 2022 Hr'g Tr. 26:20-38:14.

158. At the January 28, 2022 hearing on Azurity's motion for a preliminary injunction against Annora Pharma Private Limited's ("Annora") ANDA product ("Annora PI") in *Azurity Pharmaceuticals, Inc. v. Annora Pharma Private Limited*, C.A. No. 21-196-LPS (D Del.), Azurity's counsel told this Court that "Azurity and CoreRx settled the case and CoreRx agreed not to continue infringement."

III. AZURITY'S SUITS AGAINST BIONPHARMA AND CORERX WERE AND ARE OBJECTIVELY BASELESS

159. Azurity's exclusionary actions in filing and prosecuting the baseless First, Second, and Third Wave Suits, and the Delaware and Florida CoreRx suits, constitute wrongful and unlawful exclusionary conduct.

A. Azurity's First Wave Suits Were Baseless

160. Azurity's filing and prosecution of the First Wave Suits had the purpose and effect of blocking competition by delaying the entry of Bionpharma's ANDA product, a lower-priced, therapeutically equivalent generic substitute for Azurity's Epaned®.

161. As explained above, Azurity's First Wave Suits were objectively baseless on multiple grounds, including because Azurity indisputably was estopped from asserting the First Wave Patents against Bionpharma, and because, as Azurity knew or should have known, there existed no facts that would ever demonstrate how and why Bionpharma's ANDA product met the buffer limitation of the claims of the First Wave Patents.

162. Azurity's refusal to investigate the validity of its claims and purposeful avoidance of any such investigation before filing the First Wave Suits constituted bad faith and is itself evidence of Azurity's anticompetitive purpose, and its awareness of the lack of any objective basis for its infringement claims against Bionpharma's ANDA product.

163. Upon information and belief, Azurity filed the First Wave Suits for the purpose of securing the automatic 30-month stay, and allowing Azurity time to pursue its strategy of serially filing meritless continuation applications regardless of their inherent and obvious invalidity.

164. No reasonable litigant having a copy of Bionpharma's ANDA and the prosecution history of the First Wave Patents, as Azurity did by no later than December 2019, could have reasonably expected to prevail on the merits of Azurity's claim that Bionpharma's ANDA and ANDA product infringed the First Wave Patents.

B. Azurity's Second Wave Suit Was Baseless

165. As explained above, Azurity was able to overcome the PTO Examiner's lack of written description rejections during prosecution of the '159 application only by submitting declarations from Dr. Mosher describing enalapril liquids nowhere described in the specification of the '159 application, which is a fundamental violation of patent law—an applicant is not permitted under the law to supplement a deficient specification with post-application filing inventor declarations.

166. In obtaining the three Second Wave Patents and then asserting them against Bionpharma's ANDA product, Azurity took advantage of the Examiner's mistaken belief that it could supplement its deficient disclosure with inventor declarations submitted after its patent applications that issued into the Second Wave Patents were filed.

167. Azurity knew or should have known that the claims of the Second Wave Patents, which claimed enalapril liquids beyond the Example E liquids—the only liquids described in the specification as being stable for at least 12 months under refrigerated conditions—were invalid for lack of written description and lack of enablement.

168. No reasonable litigant having access to the prosecution history of the Second Wave Patents, the specification for those patents, and Azurity's repeated admissions during the First Wave Suits that enalapril was unpredictable and inherently unstable in liquid formulations, could reasonably expect to prevail on the merits of Azurity's infringement claims against Bionpharma in the Second Wave Suit.

169. Further, no reasonable litigant would have reasonably expected that Azurity would succeed in proving that maleic acid dissociated from enalapril maleate in Bionpharma's ANDA product could be a buffer, let alone one equivalent to the claimed citrate buffer. There is absolutely no written description in the common specification of an enalapril liquid where the only buffer is maleic acid dissociated from enalapril maleate.

C. Azurity's Third Wave Suits Are Baseless

170. As with the Second Wave Patents, Azurity took advantage of the Examiner's mistaken belief that it could supplement its deficient disclosure with inventor declarations submitted after the '587 application was filed to secure issuance of claims in the Third Wave Patents that have no written description support in the specification.

171. Azurity knows or should know that the claims of the Third Wave Patents, which claim enalapril liquids beyond the Example E liquids—including enalapril liquids with no buffers—are invalid for lack of written description and lack of enablement.

172. Moreover, Azurity, as a party to the MMSA, knows or should know that Bionpharma has a license to the Third Wave Patents pursuant to the MMSA, and that, thus, Bionpharma cannot be liable for infringement of those patents.

173. Further, Azurity knows or should know that any patent rights it has in Bionpharma's ANDA product have been exhausted by CoreRx's sale of Bionpharma's ANDA product to Bionpharma, by virtue of the fact that Azurity and CoreRx are commonly-owned affiliates.

174. No reasonable litigant having access to the prosecution history of the Third Wave Patents, the specification for those patents, and Azurity's repeated admissions during the First Wave Suits that enalapril was unpredictable and inherently unstable in liquid formulations, could reasonably expect to prevail on the merits of Azurity's infringement claims against Bionpharma in the Third Wave Suit.

D. Azurity's Suits Against CoreRx Are Baseless

175. No reasonable litigant would believe that Azurity sued CoreRx, Azurity's commonly-owned affiliate, with the intent to hold CoreRx liable for damages for alleged infringement of the Third Wave Patents, or even with the expectation that this Court or another court would enter judgment on a patentee's infringement suit against its own commonly-owned affiliate.

176. No reasonable litigant would believe there is a justiciable controversy between Azurity and CoreRx regarding CoreRx's alleged infringement of the Third Wave Patents, in light of the fact that both Azurity and CoreRx are owned by the same private equity firm, NovaQuest. In particular, no reasonable litigant in Azurity's position, with five directors who occupy five of

the seven director seats at CoreRx, would believe that it had a basis for invoking this Court's power to issue an order to CoreRx.

177. On information and belief, despite pleading for damages and demanding a jury in its complaint against CoreRx (*see, e.g.*, 21-1522 D.I. 1, Compl. at Prayer for Relief, Jury Trial Demand), Azurity has no intention of securing a damages award from, or obtaining an injunction against, its commonly-owned affiliate, CoreRx.

178. On information and belief, Azurity sued CoreRx in the Delaware and Florida CoreRx suits for at least four reasons. *First*, Azurity knew Bionpharma would need to intervene in the CoreRx suits to defend its ANDA product; thus, the Delaware and Florida CoreRx suits were filed with the intention of miring Bionpharma in never ending, objectively baseless, litigation concerning Bionpharma's ANDA product.

179. *Second*, Azurity intended to secure a sham resolution against CoreRx, through an orchestrated default (or "settlement"), that CoreRx could use as an excuse to stop performing under the contract CoreRx has to commercially manufacture and supply Bionpharma's ANDA product.

180. *Third*, upon information and belief, Azurity sued CoreRx with the intent of, through CoreRx, seeking a renegotiation of the MMSA, under the guise of CoreRx seeking an indemnity from Bionpharma for any damages awarded against CoreRx in the Delaware and Florida CoreRx suits. Upon information and belief, Azurity has had no intention of securing a damages award or an injunction against its commonly-owned affiliate, CoreRx, but intends to use, through CoreRx, feigned concern about such relief to force Bionpharma into a renegotiation of the MMSA to remove Azurity as a party by virtue of being an affiliate of CoreRx, so that it can contend that Bionpharma may no longer have a license to Azurity's Epaned® patents.

181. *Fourth*, Azurity sued CoreRx with the intention of ultimately securing an agreement from CoreRx to cutoff supply of Bionpharma's ANDA product, thereby accomplishing what it had failed to achieve thus far through its patent suits against Bionpharma.

182. The actual and intended anticompetitive effects of the Delaware and Florida suits against CoreRx are evident from the foregoing facts and CoreRx's attempt to renegotiate key terms of the MMSA with Bionpharma. Azurity, through CoreRx, seeks to remove the license Bionpharma has to any Azurity's Epaned® patents through the MMSA so that it may then assert those patents, however baselessly, without having to overcome a license defense that could shut down Azurity's Third Wave Suit quickly, and then drive Bionpharma's ANDA product from the market, not through a judgment obtained on the patent merits, but instead through the cumulative expense and distraction of patent litigation, and by entering into an unlawful agreement with CoreRx to cutoff supply of Bionpharma's ANDA product.

183. No reasonable litigant, with knowledge of the common ownership between Azurity and CoreRx, would believe that the Delaware and Florida CoreRx suits represent justiciable controversies aimed at enforcing legitimate patent rights. Instead, both actions represent back-door attempts to remove Bionpharma's ANDA product from the market.

IV. AZURITY'S SUITS AGAINST BIONPHARMA AND CORERX WERE AND ARE IN SUBJECTIVE BAD FAITH

184. As shown above, Azurity brought the First Wave Suits after refusing to even review Bionpharma's ANDA to determine whether Bionpharma's ANDA product infringed Azurity's patents. It repeatedly changed its theory of infringement in a search for a basis for its infringement claims. All the while, Azurity gained the benefit of the automatic 30-month stay on FDA approval of Bionpharma's ANDA product, which took effect automatically on the filing of the First Wave Suits, regardless of their lack of merit.

185. Further, as shown above, Azurity brought the Second Wave Suit, based on patents with the same fatal flaws as the First Wave patents, shortly before the end of the 30-month stay, in order to buttress its litigating position against Bionpharma in case this Court did not issue a judgment upholding its First Wave Suits before the 30-month stay terminated.

186. Although the First Wave and Second Wave Suits failed on the merits, as they were bound to, they succeeded in achieving a substantial part of Azurity's ultimate purpose. While it was not able to coerce Bionpharma into abandoning its ANDA product, Azurity was able to delay the launch of that product by eight months through the automatic 30-month stay that the First Wave Suits triggered. On information and belief, that eight-month delay, not a judgment on the patent merits, was the purpose of the First Wave Suit. Similarly, on information and belief, the purpose of the Second Wave Suit was not a judgment on the merits, but to continue to intimidate Bionpharma into delaying and ultimately abandoning its ANDA product.

187. Now, after losing both the First Wave and Second Wave suits, Azurity has brought the Third Wave Suit, based on patents whose obvious invalidity led this Court to deny its motion for a preliminary injunction. On information and belief, Azurity has brought this suit too not to obtain a judgment on the merits, but rather to continue to wear Bionpharma down and coerce it into abandoning its ANDA product rather than continue to incur the costs of patent litigation.

188. Finally, as shown above, Azurity brought the two infringement suits against its commonly-owned affiliate CoreRx despite the obvious absence of a justiciable controversy between them; their common owner NovaQuest, and indeed the five common directors of Azurity and CoreRx, could simply have directed CoreRx to breach its supply contract with Bionpharma without involving a court. Indeed, Azurity and CoreRx quickly agreed that CoreRx would breach its supply contract with Bionpharma, and Azurity promptly dismissed the suits voluntarily. On

information and belief, Azurity brought these suits not in order to win an injunction against, or damages from, its affiliate CoreRx, but rather to paper over CoreRx's intended breach of its supply contract obligations to Bionpharma, and to further embroil Bionpharma in costly and distracting litigation, all in order to force Bionpharma's ANDA product out of the market.

V. BUT FOR AZURITY'S SHAM FIRST WAVE SUITS, BIONPHARMA WOULD HAVE LAUNCHED ITS ANDA PRODUCT BY DECEMBER 2020

189. If Azurity had never instituted the sham First Wave Suits, and secured a 30-month stay based on those sham suits, Bionpharma's ANDA product—the first lower-priced, AB-rated generic equivalent to Epaned®—would have been commercially launched no later than December 28, 2020, when Bionpharma received tentative approval for its ANDA.

190. Had Bionpharma been able to launch its ANDA product on December 28, 2020, it would have carried out its plan to price its ANDA product at a substantial discount compared to Epaned®, providing consumers for the first time with a lower-cost, but therapeutically identical, competitive alternative. Upon information and belief, Azurity prices Epaned to consumers at approximately $560 per bottle; Bionpharma would have priced its ANDA product at a fraction of that. Bionpharma's ANDA product is currently priced at approximately [redacted] per bottle.

191. Bionpharma's plan was typical of the competitive impact of generic entry. Generic drugs are typically sold at substantial discounts from the price of the branded RLD. The first AB-rated generic drug that enters the market is generally priced at a significant discount to the RLD, capturing a substantial amount of the RLD's market share, and, as additional AB-rated generic drugs enter the market, generic drug prices continue to fall.

192. Competition from generic drugs thus generates large savings for consumers. The Association for Accessible Medicines reported that use of generic and biosimilar versions of

brand-name drugs and therapeutics, respectively, saved the U.S. healthcare system $313 billion in 2019 alone.

193. Absent Azurity's unlawful anticompetitive conduct, Bionpharma likely would have captured a significant volume of enalapril maleate oral solution sales within days of FDA approval. Just as when Bionpharma actually launched its ANDA product on August 17, 2021, pharmacies and other customers would have placed large orders for Bionpharma's ANDA product on December 28, 2020, or earlier, as these customers would have had an incentive to build up a sufficient inventory of Bionpharma's lower-priced ANDA product to meet demand. Consumers would have benefited by as much as $4.9 million during this period, while Bionpharma would have enjoyed a modest profit on its competitive sales.

194. But because of the automatic 30-month stay, FDA could not issue a final approval for Bionpharma's ANDA until the earlier of April 30, 2021 and a final judgment in Bionpharma's favor. And on December 28, 2020, C.A. No. 18-1962, the first of the First Wave Suits, was not yet resolved. Because of Azurity's filing of the sham First Wave Suits, the 30-month stay barred FDA approval of Bionpharma's ANDA product, and thus the product's launch, from December 28, 2020 to at least April 29, 2021—the date of entry of final judgment in the First Wave Suits. Even after the entry of judgment, Azurity's filing of the First Wave and Second Wave Suits caused further delay in that launch until August 17, 2021, when Bionpharma's ANDA product received FDA final approval. During that period, consumers were denied the benefit of free and open competition from Bionpharma, and instead remained subject to Azurity's monopoly power. And over that the same period Bionpharma was prevented from enjoying the modest profit it would have realized from offering a competitive alternative to the market.

VI. AZURITY'S MONOPOLY POWER IN THE RELEVANT MARKET

195. The relevant product market in which to assess the anticompetitive effect of Azurity's conduct is the market for ready-to-use 1 mg/mL enalapril maleate oral solutions approved by the FDA for prescription use in pediatric and adult patients ("1 mg/mL RTU enalapril maleate oral solution products"). This relevant product market includes only Epaned® and any therapeutically equivalent, AB-rated prescription 1 mg/mL ready-to-use enalapril maleate oral solution. At this time, Bionpharma's ANDA product is the only other product in the relevant market besides Epaned®.

196. Azurity itself has confirmed this definition of the relevant market. At the hearing on the Annora PI, Azurity's counsel told this Court that, with CoreRx having "agreed" not to honor its contract to supply Bionpharma, "the status quo is that the market is returning to a one-product market, that product being Azurity's Epaned," and that "the status quo right now is a single product, Azurity's brand product, on the market." *Azurity Pharm., Inc. v. Annora Pharma Pvt. Ltd.*, C.A. No. 21-196-LPS (D. Del.), Jan. 28, 2022 Hr'g Tr. 17:18-20, 20:22-23. In fact, in ruling on the Annora PI application, the Court found that "as or today, it is true that Epaned is the only product in a ready-to-use liquid enalapril market." *Id*. at 69:13-14.

197. Azurity's admissions of a "one-product market" necessarily mean that the relevant product market excludes all products other than Epaned® and its generic equivalents. And in this action Azurity has stressed this point explicitly, stating that "there is ***no*** acceptable alternative to Epaned®." 21-1286 D.I. 52-6, Supplemental Decl. of Amit M. Patel ¶ 24 (emphasis in original). Azurity's irreparable harm expert has argued that other products are not reasonably interchangeable with Epaned® and therapeutically equivalent 1 mg/mL RTU enalapril maleate oral solution products, due to, among other factors, use, qualities, characteristics, and/or distinct

customers or end uses (namely, children and elderly patients). According to Azurity, numerous other hypertension drugs are not available in oral solution form, and therefore cannot compete with Epaned®.

198. Enalapril is an old drug originally approved in the early 1980's as a tablet formulation. Over time, there arose a demand in certain patient populations for more easily administrable enalapril formulations, such as children and elderly patients who cannot swallow tablets.

199. According to Azurity, prior to FDA approval of Epaned®, children and elderly patients looking for more easily administrable enalapril were relegated to "unapproved compounded drugs," whereby pharmacists would crush enalapril tablets and mix them with diluent to form enalapril liquids, which suffered from numerous drawbacks, including a lack of uniform dosing and stability. D.I. 25-8, Decl. of Amit M. Patel ¶¶ 38-39.

200. Prior to Bionpharma's launch, Azurity touted Epaned® as "the ***first and only*** ready-to-use enalapril solution." D.I. 52-6, Supplemental Decl. of Amit M. Patel ¶ 24 (emphasis in original).

201. Once Epaned® became available, compounded enalapril formulations were no longer a viable competitive alternative. Azurity represents that the "FDA has counseled that unapproved compounded oral formulations are generally disallowed as a matter of law where, as here, there is an FDA-approved ready-to-use formulation." *Id*.

202. Epaned® and Bionpharma's ANDA product are indicated in adults and children older than one month and are available only by prescription.

203. Bionpharma's ANDA product is therapeutically equivalent with and AB-rated to, and thus reasonably interchangeable with, and has a strong cross-elasticity of demand with, Epaned®.

204. In contrast, a small, but significant, non-transitory price increase for 1 mg/mL RTU enalapril maleate oral solution products above competitive levels would not cause a loss of sales to other therapies sufficient to make the price increase unprofitable.

205. There are substantial barriers to entry into the market for 1 mg/mL RTU enalapril maleate oral solution products, including FDA's regulatory requirements and the substantial time and expense required to develop an ANDA for a generic product therapeutically equivalent and AB-rated to Epaned®.

206. Azurity confirmed these entry barriers at the hearing on the Annora PI. There, Azurity's counsel told the Court that obtaining approval of an ANDA version of Epaned® "would require challenging Azurity's patents," and that "such cases frequently require years to resolve." And, casting doubt on Bionpharma's ability to compete in the relevant market once CoreRx "agreed" to cease supplying it, she also confirmed that qualification of a supplier with the FDA is "an uncertain and lengthy process."

207. The relevant geographic market is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States determines what products can compete in any given market for pharmaceutical products, and federal law and regulations drastically limit the ability of suppliers of even FDA-approved products into the United States from other countries. Within the United States, the fact that the marketing, sales, and distribution of pharmaceuticals occurs on a nationwide basis confirms that the geographic market is national.

208. For purposes of this litigation, then, the market for the sale of 1 mg/mL RTU enalapril maleate oral solution products in the United States (the "Relevant Market") constitutes a relevant market.

209. Azurity has confirmed to this Court that it possessed monopoly power in the Relevant Market prior to Bionpharma's launch, and will regain monopoly power if it succeeds in driving Bionpharma out of the market. As Azurity's counsel told this Court at the Annora PI hearing:

> The current status quo is that Azurity's brand product is on the market and one generic product belonging to Bionpharma . . . was launched in August of last year. And in November of last year, the supplier of Bionpharma's product, a company called CoreRx, stopped its supply to Bionpharma. Thus the status quo is that the market is returning to a one-product market, that product being Azurity's Epaned.

210. Azurity's monopoly power in the Relevant Market is evidenced by, among other factors, its prior pricing actions, its dominant market share, and its own confirmation to the Court that, once Bionpharma is removed from the Relevant Market, Azurity will be able to sell Epaned at the monopoly price.

211. Azurity's monopoly power is demonstrated by direct evidence of its ability to price well above competitive levels prior to launch of Bionpharma's ANDA product. According to Azurity's irreparable harm expert, Dr. Jeffrey Stec, Epaned®'s average net revenues (gross revenues minus discounts, allowances, returns, and commissions) in 2020 were approximately [redacted] per unit. D.I. 52-3, Reply Decl. of Jeffrey A. Stec, Ph.D. ("Reply Stec Decl.") ¶ 16. In contrast, since its August 2021 launch, Bionpharma's per-unit net revenues have been about [redacted] below Azurity's: According to Dr. Stec, "Bionpharma's weighted average net revenue per unit," from August 17, 2021 through August 31, 2021, "is approximately [redacted]." *Id.* Nothing besides monopoly power explains the difference between Azurity's and Bionpharma's prices. The

products' quality is the same, and Bionpharma does not have access to unique efficiencies that give it a pricing advantage over Azurity. Had Azurity not possessed monopoly power, it would not have been able to price at so far above Bionpharma's post-launch price.

212. Azurity's monopoly power prior to Bionpharma's launch is also evident from the impact that Bionpharma's launch had on Azurity's own unit sales, prices and profits. According to Dr. Stec, from August 2021 (the month in which Bionpharma launched its ANDA product), to September 2021 (the first full month of sales of Bionpharma's ANDA product), "the units, gross revenues, net revenues, and gross margin of Epaned® decreased by approximately [redacted]." *Id.* ¶ 10. Total prescriptions of Epaned® declined from [redacted] (the last full month of Epaned® sales prior to launch of Bionpharma's ANDA product) to [redacted] in September 2021. *Id.*

213. Had Azurity been selling in a competitive market before Bionpharma's launch, Bionpharma's entry likely would have had only an incremental impact on Azurity's unit sales, prices and profits, which already would have been a function of competition. Instead, Bionpharma's entry drastically reduced each of these measures for Azurity, which was facing competition for the first time.

214. Similarly, at the hearing on the Annora PI, Azurity's counsel argued that, after the Relevant Market returned to a monopoly, "Azurity will suffer irreparable harm if Annora launches its product," which would again present "direct competition" to Epaned®. *Azurity Pharm., Inc. v. Annora Pharma Pvt. Ltd.*, C.A. No. 21-196-LPS (D. Del.), Jan. 28, 2022 Hr'g Tr. 21:2-5. According to Azurity's economic expert (as recounted by Azurity's counsel), this irreparable harm would occur because Annora's ANDA product "will be sold at a lower price than" Epaned®, and in turn, "[t]hose lower price sales will result in price erosion to Azurity's revenue." *Id.* at 21:21-24.

215. Azurity's counsel warned further that, in response to Annora's ANDA product, "Azurity would be forced to launch an authorized generic." *Id*. at 22:5-7. And, according to Azurity's counsel, Azurity's economic expert's sworn declaration stated that "such an authorized generic launch would lead to further price erosion." *Id*. at 22:7-9. The Court agreed, finding that Annora's ANDA product "would, almost certainly, if introduced exert a downward pressure on the price of Epaned," and that Azurity's authorized generic "will also exert downward pressure." *Id*. at 69:15-21.

216. This price erosion, of which Azurity itself persuaded the Court at the Annora PI hearing, can mean only one thing: that after excluding Bionpharma from the market, Azurity, with the "single product . . . on the market" (*id*. at 20:22-23), will be charging monopoly prices for Epaned®. In a competitive market, the entry of one or even two competitors would decrease prices to the level of "irreparable harm." The only reason Azurity could suffer such harm is because, until new ANDA versions of Epaned® enter, it will have, and will be exerting, monopoly power in the Relevant Market.

VII. ANTICOMPETITIVE EFFECTS OF AZURITY'S CONDUCT

A. Harm to Competition

217. Azurity's wrongful filing and prosecution of the First and Second Wave Suits was exclusionary in purpose and effect and unreasonably restrained competition. Azurity abused and manipulated the Hatch-Waxman regime through the wrongful filing and prosecution of the First and Second Wave Suits for exclusionary and anticompetitive purposes, with the direct and intended effect that FDA's approval of Bionpharma's ANDA was improperly delayed, to the detriment of Bionpharma and consumers alike.

218. But for Azurity's wrongful filing and prosecution of the First Wave Suits, the FDA would have approved Bionpharma's ANDA by late December 2020. On December 28, 2020, when FDA tentatively approved Bionpharma's ANDA, the only barrier to final approval was the 30-month stay automatically triggered by Azurity's objectively baseless First Wave Suits. But for the automatic 30-month stay, Bionpharma's ANDA would have received final approval on December 28, 2020, and Bionpharma would have commenced selling its ANDA product at that time at a substantial discount compared to the prices for branded Epaned®, resulting in enormous savings to patients who rely on 1 mg/mL RTU enalapril maleate oral solution products.

219. Instead, as a direct and proximate result of Azurity's improper and exclusionary conduct, consumers in the United States have paid and may once again pay higher prices for 1 mg/mL RTU enalapril maleate oral solution products. Azurity already improperly excluded Bionpharma's ANDA product from the market for 1 mg/mL RTU enalapril maleate oral solution products starting in late December 2020 until August 2021, when Bionpharma obtained final FDA approval after this Court's decision in the First Wave Suits terminated the 30-month stay. Now, Azurity seeks—through the Third Wave Suits and, until recently, through the Delaware and Florida CoreRx suits—to improperly remove Bionpharma's ANDA product from the market with sham litigation, all to the detriment of consumers and Bionpharma.

B. Harm to Bionpharma

220. As a direct and proximate cause of Azurity's filing and prosecution of the sham First Wave Suits, Bionpharma has suffered significant competitive harm. Azurity's wrongful and exclusionary conduct in connection with the First Wave Suits caused a substantial delay in the approval of Bionpharma's ANDA, causing a substantial and unjustified delay in the commencement of Bionpharma's sales of Bionpharma's ANDA product.

221. Absent Azurity's anticompetitive conduct in connection with the sham First Wave Suits, Bionpharma projects that it would have sold approximately [redacted] of its ANDA product within the first four months of 2021 after receiving final FDA approval to fill initial orders for its ANDA product. Those sales would have likely produced net income of approximately [redacted] million for Bionpharma. For the period of December 28, 2020 until Bionpharma was finally able to launch, Bionpharma projects that it would have sold approximately [redacted] million of its ANDA product; those sales would likely have produced [redacted] million in net income for Bionpharma. Instead, Azurity kept those sales for itself at its monopoly-level prices and profits. Moreover, by virtue of having to defend against Azurity's sham First, Second, and Third Wave Suits, as well as the Delaware and Florida CoreRx suits, Bionpharma has sustained well over [redacted] in legal fees and costs.

222. Although Bionpharma has since launched its ANDA product, Bionpharma continues to be threatened by Azurity's anticompetitive conduct in connection with the objectively baseless Third Wave Suits and, until recently, the Delaware and Florida CoreRx suits. Like generic products generally, Bionpharma's ANDA product does not produce profit margins anything like those of Azurity's for Epaned®. On information and belief, Azurity is aware that Bionpharma's likely net profits from its ANDA product are low enough that sustained patent infringement litigation, and its attendant costs, is likely to discourage Bionpharma from continuing to compete. And other ANDA filers for generic Epaned® will see from Bionpharma's experience that the game is not likely to be worth the candle.

223. These injuries that Bionpharma has incurred, and continues to be threatened with, due to Azurity's wrongful and exclusionary conduct constitute redressible antitrust injury.

COUNT I
(Declaratory Judgment of Invalidity of the '023 Patent)

224. Bionpharma realleges and incorporates by reference the preceding paragraphs of these Counterclaims as though fully set forth herein.

225. There is an actual, substantial, and continuing case or controversy between Bionpharma and the Azurity regarding, *inter alia*, the invalidity of the '023 patent.

226. The claims of the '023 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including but not limited, to 35 U.S.C. §§ 101, 102, 103, and/or 112.

227. Claim 1 of the '023 patent, the sole independent claim, recites as follows:

> 1. A stable oral liquid formulation, consisting essentially of:
>
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
>
> (ii) a sweetener;
>
> (iii) a preservative, wherein the preservative comprises sodium benzoate, a paraben or a mixture of parabens;
>
> (iv) water; and
>
> (v) optionally a flavoring agent;
>
> wherein the formulation is stable at about 5±3° C. for at least 12 months; and wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

228. The specification of the '023 patent does not contain a written description of the subject matter claimed in the '023 patent, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use the same. Specifically, nowhere in the specification of the '023 patent is there any description of an enalapril liquid without a buffer, including an enalapril liquid without

a buffer that would meet the stability limitations recited in the claims. Moreover, Azurity argued during the prosecution history of the '023 patent, and in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma, Inc.*, Nos. 18-1062-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), that the stability of enalapril oral liquid formulations was unpredictable and that only through preparation and testing of formulations could a person of ordinary skill ascertain what combination of ingredients would lead to stable formulations. There is nothing in the specification of the '023 patent demonstrating to a person of ordinary skill in the art that the named inventors were in possession of the claimed enalapril oral liquid formulations as of the filing date of the application that issued into the '023 patent, and the claims of the '023 patent are therefore invalid for lack of written description.

229. The claims of the '023 patent are also invalid for lack of enablement, as the '023 patent specification does not describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation. Specifically, nowhere in the specification of the '023 patent is there any data provided or rationale advanced demonstrating that the claimed enalapril oral liquid formulations, some of which do not include buffers, would be stable at refrigerated conditions for the storage periods recited in the claims. Moreover, Azurity argued during the prosecution history of the '023 patent, and in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma, Inc.*, Nos. 18-1062-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.), that the stability of enalapril oral liquid formulations was unpredictable and that only through preparation and testing of formulations could a person of ordinary skill ascertain what combination of ingredients would lead to stable formulations. It would require undue experimentation, including the preparation and testing for 12 months or longer of potentially tens of thousands of enalapril oral liquid

formulations, for a person of skill in the art to determine what formulations meet the recited stability requirements and thus fall within the scope of the claims of the '023 patent.

230. The claims of the '023 patent are also obvious and therefore invalid under 35 U.S.C. § 103 over the following references, which disclose each element of the claims of the '023 patent: (1) the 2014 Prescribing Information for the Epaned® Kit; (2) Ip and Brenner, 16 ANALYTICAL PROFILES OF DRUG SUBSTANCES 207, 236 (1987); (3) Raymond C. Rowe et al., HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 605-610 (6th Ed. 2009); (4) U.S. Food and Drug Administration, *Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products* (Nov. 2003, Rev. 2; and (5) U.S. Patent No. 8,568,747 B1. A POSA would be motivated to combine these references to formulate a ready-to-use enalapril liquid formulation that is stable for at least 12 months under refrigerated conditions, to overcome the problems associated with prior art enalapril liquid formulations, such as the Epaned® Kit, including lack of long-term stability. There are no secondary considerations of non-obviousness that have a nexus to the '023 patent claims and that are commensurate in scope with those claims.

231. Bionpharma is entitled to a judicial declaration that the claims of the '023 patent are invalid.

COUNT II
(Declaratory Judgment of Non-Infringement of the '023 Patent)

232. Bionpharma realleges and incorporates by reference the preceding paragraphs of these Counterclaims as though fully set forth herein.

233. There is an actual, substantial, and continuing case or controversy between Bionpharma and the Azurity regarding, *inter alia*, non-infringement of the claims of the '023 patent.

234. Bionpharma's ANDA, and the manufacture, use, offer for sale, sale, importation, and/or marketing of Bionpharma's ANDA product, has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '023 patent, either literally or under the doctrine of equivalents. For instance, any claim from Azurity that Bionpharma's ANDA or ANDA product infringes the '023 patent is barred on claim preclusion grounds, as such a claim would assert the same cause of action previously litigated and resolved in Bionpharma's favor in connection with *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS, 19-1067-LPS, and 20-1256-LPS (D. Del.). Furthermore, certain claims of the '023 patent require sodium benzoate as a preservative, such as '023 patent claims 17, 18, and 20; Bionpharma's ANDA product does not contain sodium benzoate. Furthermore, Bionpharma has a license to the patents-in-suit pursuant to the MMSA, because Azurity is an affiliate of CoreRx under that agreement. Furthermore, any patent rights Azurity has in connection with Bionpharma's ANDA product have been exhausted by CoreRx's sale of Bionpharma's ANDA product to Bionpharma, because of the common ownership between Azurity and CoreRx, and because Azurity is an affiliate of CoreRx.

235. Bionpharma is entitled to a judicial declaration that the filing of its ANDA, and the manufacture, use, offer for sale, sale, importation, and/or marketing of Bionpharma's ANDA product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '023 patent, either literally or under the doctrine of equivalents

COUNT III
(Monopolization (15 U.S.C. §§ 2 and 15))

236. Bionpharma repeats and incorporates herein by reference its counterclaim paragraphs above.

237. Prior to the launch of Bionpharma's ANDA product on August 17, 2021, Azurity possessed monopoly power in the Relevant Market.

238. The Relevant Market is the market for 1 mg/mL RTU enalapril maleate oral solution products. This Relevant Market includes only Epaned® and any therapeutically equivalent, AB-rated prescription 1 mg/mL ready-to-use enalapril maleate oral solution. At this time, Bionpharma's ANDA product is the only other product in the Relevant Market besides Epaned®.

239. Azurity has engaged in exclusionary and predatory conduct, including, without limitation, the filing and prosecution of the sham First Wave Suits.

240. Azurity's wrongful conduct in instituting and prosecuting the sham First Wave Suits allowed it to maintain its monopoly power by keeping Bionpharma's ANDA product out of the Relevant Market after Bionpharma received tentative FDA approval, improperly delaying the entry of Bionpharma's ANDA product and denying consumers the benefits of competition in the Relevant Market.

241. Through its institution and prosecution of the sham First Wave Suits, Azurity has caused substantial loss and injury to Bionpharma and market-wide competitive harm to consumers due to Azurity's violation of the antitrust laws.

242. Azurity's conduct in instituting and prosecuting the sham First Wave Suits was the actual and proximate cause of the loss and injury to Bionpharma and the market-wide competitive harm to consumers.

243. The injury Bionpharma sustained from being improperly excluded from the Relevant Market from late December 2020 to August 17, 2021 was a direct result of the anticompetitive nature of Azurity's conduct and constitutes antitrust injury.

244. Azurity's conduct has occurred in interstate commerce.

COUNT IV
(Attempted Monopolization (15 U.S.C. §§ 2, 15, and 26))

245. Bionpharma repeats and incorporates herein by reference its counterclaim paragraphs above.

246. There is a dangerous probability that, through instituting and prosecuting the sham Third Wave Suits and, until recently, the Delaware and Florida CoreRx suits, that Azurity may regain monopoly power in the Relevant Market.

247. The Relevant Market is the market for 1 mg/mL RTU enalapril maleate oral solution products. This Relevant Market includes only Epaned® and any therapeutically equivalent, AB-rated prescription 1 mg/mL ready-to-use enalapril maleate oral solution. At this time, Bionpharma's ANDA product is the only other product in the Relevant Market besides Epaned®

248. Azurity has engaged in exclusionary and predatory conduct, including, without limitation, the filing and prosecution of the sham Third Wave Suits and the sham Delaware and Florida CoreRx suits.

249. Upon information and belief, Azurity—through institution of the sham Third Wave Suits and the sham Delaware and Florida CoreRx suits—has the specific intent to once again monopolize the Relevant Market.

250. Through its institution and prosecution of the sham Third Wave Suits and the sham Delaware and Florida CoreRx suits, and the attendant costs and disruption imposed on Bionpharma, Azurity has caused and will continue to cause substantial loss and injury to Bionpharma, and creates a dangerous probability of competitive harm to consumers from Azurity's recovery of monopoly power in the Relevant Market.

251. Azurity's conduct in instituting and prosecuting the sham Third Wave Suits and the sham Delaware and Florida CoreRx suits is the actual and proximate cause of potential loss and injury to Bionpharma and competitive harm to consumers.

252. Azurity's conduct has occurred in interstate commerce.

PRAYER FOR RELIEF

WHEREFORE, Bionpharma respectfully prays for judgment in its favor and against Azurity:

a) Declaring that the claims of the '023 patent are invalid;

b) Declaring that the filing of Bionpharma's ANDA, and the manufacture, use, sale, offer for sale, importation, and/or marketing of Bionpharma's ANDA product has not infringed, does not infringe, and will not infringe, either directly or indirectly, any valid and/or enforceable claim of the '023 patent either literally or under the doctrine of equivalents;

c) Ordering that Azurity's First Amended and Supplemental Complaint for Patent Infringement be dismissed with prejudice and judgment entered in favor of Bionpharma;

d) Declaring this case exceptional and awarding Bionpharma its reasonable attorney fees and costs under 35 U.S.C. § 285;

e) Awarding damages for Bionpharma's lost sales of generic enalapril maleate oral solution, 1 mg/mL due to Azurity's violations of the antitrust laws, trebling those damages, awarding prejudgment interest on the damages, including without limitation the amount trebled, and a reasonable attorney's fee, all pursuant to 15 U.S.C. § 15(a);

f) Enjoining Azurity, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys from further attempts to monopolize the Relevant Market, including by further pursuit of the Third Wave Suits; and

g) Awarding such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Bionpharma hereby demands a trial by jury on all issues so triable.

Dated: February 17, 2022

/s/ *John C. Phillips, Jr.*
John C. Phillips, Jr. (#110)
Megan C. Haney (#5016)
PHILLIPS, MCLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
mch@pmhdelaw.com

Of Counsel:

Andrew M. Alul
Roshan P. Shrestha, Ph.D.
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
312-527-4000
aalul@taftlaw.com
rshrestha@taftlaw.com

Aaron M. Johnson
TAFT STETTINIUS & HOLLISTER LLP
2200 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
612-977-8400
ajohnson@taftlaw.com

Christopher J. Kelly
MAYER BROWN LLP
Two Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2112
(650) 331-2000
cjkelly@mayerbrown.com

Attorneys for Defendant Bionpharma Inc.

CERTIFICATE OF SERVICE

The undersigned certifies and states that a true and accurate copy of the foregoing DEFENDANT BIONPHARMA'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO FIRST AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT was served on the counsel for Plaintiff by electronic mail on February 17, 2022, to:

Jack B. Blumenfeld
Megan E. Dellinger
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
jblumenfeld@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

Natalie J. Morgan
Evan T Sumner
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real Suite 200
San Diego, CA 92130-3002
(858) 350-2300
nmorgan@wsgr.com
esumner@wsgr.com

Wendy L. Devine
Kristina M. Hanson
Nicholas S Halkowski
WILSON SONSINI GOODRICH & ROSATI
One Market Plaza, Spear Tower, Suite 3300
San Francisco, CA 94105
(415) 947-2000
wdevine@wsgr.com
thanson@wsgr.com
nhalkowski@wsgr.com

Granville C Kaufman
Ty W Callahan
WILSON SONSINI GOODRICH & ROSATI
633 West Fifth Street, Suite 1550
Los Angeles, CA 90071
(323) 210-2900
gkaufman@wsgr.com
tcallahan@wsgr.com

/s/ *John C. Phillips, Jr.*
John C. Phillips, Jr. (#110)
Phillips, McLaughlin & Hall, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com